

Application No. 10/775,883  
Response dated August 24, 2006  
Reply to Office Action of August 2, 2006

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### REMARKS

Claims 1-17 are pending in this application. The Examiner contends that this Application contains the following inventions or groups of inventions:

Group I, claims 1-5 drawn to compounds of the formula of claim 1;

Group II, claims 6-16 drawn to methods of modulation or regulation of gene expression; and

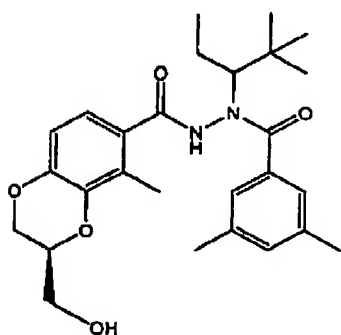
Group III, claim 17 drawn to a method of producing polypeptides using cells.

The Examiner suggested that the inventions listed as Groups I-III are distinct from one another as they are unrelated because they are not disclosed as capable of use together and they have different designs. Specifically, the examiner suggests that the Groups comprise a compound, a method of modulating gene expression and a method of polypeptide synthesis and they have different designs and modes of operations.

In reply, and solely to be responsive to the Examiner's requirement, Applicants provisionally elect Group I, claims 1-5, drawn to compounds of the formula of claim 1. The Examiner has also requested that Applicants make a species elections.

### Election of Species

Applicants provisionally elect:



wherein:

$R^1$  = ethyl,  $R^2$  = t-Bu,  $R^3$  = H,  $R^4$  = methyl,  $R^5$ ,  $R^6$  = -OCH( $R^9$ )-CH( $R^{10}$ )O-  
 $R^7$  = H,  $R^8$  = H,  $R^9$  = CH<sub>2</sub>OH,  $R^{10}$  = H, X, X' = O, Y = 3,5-di-methylphenyl.

Under 35 U.S.C. § 121, restriction may be required if "two or more independent and distinct inventions are claimed in one application." According to the interpretation

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provided in MPEP § 802.01, the term "independent" means that "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect..." The term "distinct" is defined in MPEP § 801.02 as meaning that "two or more subjects as disclosed are related... but are capable of separate manufacture, use or sale as claimed, and ARE PATENTABLE (novel and unobvious) OVER EACH OTHER..." (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

The mere existence of two or more independent or distinct inventions in one application is not sufficient to justify a restriction requirement.

According to the guidelines in MPEP § 803, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

Further, all of these claims involve a fundamental determination of the novelty of this class of diacylhydrazines, and their use in modulating the expression of a target gene via an inducible gene expression system. To the extent that this determination would be made, it is submitted that a preponderantly coextensive search would result. In particular, an exhaustive search for diacylhydrazine ligands of the present invention would encompass other hydrazine ligands. Performing an entire search covering a gene expression system and diacylhydrazine ligands is less burdensome on the Examiner than separate searches, which necessarily involve duplication of searching efforts.

Applicants respectfully submit that prosecution of the claims of Groups I and II designated by the Examiner in the present Application is appropriate. Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added). The groups designated by the Examiner fail to define products with

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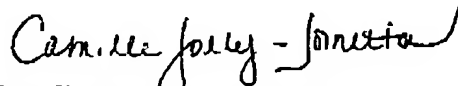
properties so distinct as to warrant separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application.

Thus, Applicants submit that the search and examination of claims 1-16 can be made without serious burden. Applicants respectfully submit that conjoint examination and inclusion of these claims of the present application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction of Groups I and II is believed to be in order.

### Conclusion

Applicants respectfully submit that claims 1-16 are related as they are drawn to compounds can be used with the method to regulate the gene expression system. Further, insufficient reasons have been put forth to support a restriction between the inventions of Groups I and II. In view of the above remarks, Applicants respectfully request reconsideration and withdrawal of the finding of lack of relatedness between the claims of Groups I and II. These claims should fairly be examined in a single application. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional application(s) directed to the subject matter of the non-elected claims. If a telephone interview would be of assistance in advancing prosecution of this application, Applicants' agent invites the Examiner to contact her at (610) 650-8734 ext. 104.

Respectfully submitted,

  
Camille Jolly-Tornetta, Ph.D.  
Registration No. 48,592

RheoGene, Inc.  
2650 Eisenhower Avenue  
Norristown, PA 19403  
Telephone: (610) 650-8734  
Fax: (610) 650-8755

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